

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Roberto Fagnani et al.	
Serial No.: 10/054,728	Group Art Unit: 1639
Filed: October 25, 2001	Examiner: My Chau T. Tran
Title: Three Dimensional Format Biochips	Conf. No.: 3521
Attorney Docket No.: 71726/6776	

Commissioner for Patents
P.O. Box 1450
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DECLARATION PURSUANT TO 37 C.F.R. § 1.132

I, Yehudit Falcovitz-Gerassi of San Diego, California, declare as follows:

1. I hold a Masters of Science degree in Bioengineering from the University of California, San Diego, granted in 2000.
2. I am presently employed at Biocept, Inc. in San Diego, California, where I have worked since August 2000. During my period of employment, I have worked extensively in the field of microarrays wherein three dimensional hydrogel microspots to which binding entities are attached are deposited on a flat substrate, e.g. glass slide.
3. I am the co-inventor of the subject matter described in U.S. Serial No. 10/922,387, filed August 19, 2004, and entitled "Alleviation of Non-Specific Binding in Microarray Assays".
4. I understand that during the prosecution of the above-entitled U.S. patent application, the meaning of the term "non-specific protein absorption" or "non-specific protein binding" has been called into question. Such is terminology that is well-known in this art. It simply refers to the adherence of any and all proteins to the surface of a microarray substrate, which proteins are then responsible for background noise when a microarray is imaged. The following description appears in my pending application:

"non-specific binding of proteins to a microarray substrate increases the background noise when the microarray is imaged or the signal is generated on the microspots or otherwise read; this makes it difficult to detect and distinguish signals being obtained from labels which should be specifically bound to particular spots, particularly in instances where the signal is relatively weak because background noise interferes and prevents obtaining precise readings".

5. The use of the term "non-specific" is meaningful from the standpoint that it is used to distinguish such background binding from the desired precise binding that desirably will occur only when a specific protein target in a sample is sequestered by a binding entity or probe immobilized in a discrete microspot formed of a different material that is a part of the array. Accordingly, a coating is frequently applied to the areas of the array surrounding the discrete microspots to block such potential non-specific binding, and such coating is of a character that it resists the binding/attachment of all proteins.

6. In my opinion, one having ordinary skill in this art would clearly not imply that a coating which is characterized as being "resistant to nonspecific protein absorption" would yet be useful in binding to one specific protein. Proteins are sequences of amino acid residues, and coatings characterized as so being resistant would not be able to distinguish one protein from another. Such is indeed the purpose of the Braatz et al. coating, namely, to coat items for laboratory or medical use in environments where proteins are omnipresent and the desire is to avoid attachment of all proteins, to avoid occlusion, clogging, etc. (see column 2, lines 32-43).

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this Declaration is directed.


Yehudit Falcovitz-Gerassi